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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,008	10/14/2003	Jochen Heinz	72570	4299
23872	7590	07/03/2007		
MCGLEW & TUTTLE, PC P.O. BOX 9227 SCARBOROUGH STATION SCARBOROUGH, NY 10510-9227			EXAMINER DESANTO, MATTHEW F	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 07/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/685,008	Applicant(s) HEINZ ET AL.	
	Examiner Matthew F. DeSanto	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-20 are being interpreted as product by process claims. Claims 1-20 recite "single injection molded" and claim 3 recites "welded." These limitations are being viewed as product by process limitations (see MPEP section 2112.01).

3. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen et al. (USPN 6,6520,935) and further in view of Whitney (USPN 4,220,151).

Jansen et al. discloses a tamper-evident closure for a syringe, said closure comprising: a syringe cylinder having a plastic connection end provided with a Luer connection; and a cap and a frangible web formed as a single injection molded plastic part, said cap engaging over at least said Luer connection; wherein said frangible web is connected to said connection end by one of a material-fit connection and an adhesive bond (see figure 4, 5, 7, 8 and entire reference).

Whitney discloses a Luer needle connector that can be made from polypropylene or the like, because of the added benefit that polypropylene provides.

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to modify the device of Jansen et al. with the teachings of Whitney because of the added benefit polypropylene provides. According to Whitney in background section, Whitney describes that it is well known in the medical art to make Luer connectors out of polypropylene because the polymer doesn't interact with the drugs and/or medicament that are used in syringe and the polymer is a relatively tough material (Column 1, lines 20-25). Thus Whitney showed that it would have been obvious to modify the device of Jansen et al. or Reinhard et al. due to the fact that it is well known in the medical art to make Luer connectors and syringes out of polypropylene as well as the added benefit that is taught in Whitney.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinhard et al. (USPN 6,280,418) and further in view of Whitney (USPN 4,220,151).

Reinhard et al. discloses a tamper-evident closure for a syringe, said closure comprising: a syringe cylinder having a plastic connection end provided with a Luer connection; and a cap and a frangible web formed as a single injection molded plastic part, said cap engaging over at least said Luer connection; wherein said frangible web is connected to said connection end by one of a material-fit connection and an adhesive bond (see figure 3 and entire reference), but fails to explicitly state the steps of injecting molding and the specific polymers and materials that the syringe, and closure are made from.

Whitney discloses a Luer needle connector that can be made from polypropylene or the like, because of the added benefit that polypropylene provides.

Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Reinhard et al. with the teachings of Whitney because of the added benefit polypropylene provides. According to Whitney in background section, Whitney describes that it is well known in the medical art to make Luer connectors out of polypropylene because the polymer doesn't interact with the drugs and/or medicament that are used in syringe and the polymer is a relatively tough material (Column 1, lines 20-25). Thus Whitney showed that it would have been obvious to modify the device of Jansen et al. or Reinhard et al. due to the fact that it is well known in the medical art to make Luer connectors and syringes out of polypropylene as well as the added benefit that is taught in Whitney.

Response to Arguments

5. Applicant's arguments filed 4/17/07 have been fully considered but they are not persuasive.
6. The applicant argues that the tamper-evident closure is not formed from plastic and is not a one-piece molded plastic element. The product by process limitations are viewed with regards to MPEP section 2112.01 and therefore as long as the same structure is present, the prior art inherently reads on the limitations or are an obvious modification, which would be a well known modification in the art.

Art Unit: 3763

7. With regards to the arguments drawn to the closure being a one-piece cap and web, the examiner respectfully disagrees since each reference shows the cap and web as a one-piece element before use, after the closure has been put together.

8. The examiner would also like to note that both Jansen et al. and Reinhard et al. disclose plastic as the materials that make up the closure. Jansen et al. in the summary of the invention and in Column 5, while Reinard et al. also discloses plastic as the material making up the cap, web and closure (in the summary and Column 5).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative call 800-786-9199 or 571-272-1000.

Matthew DeSanto
Art Unit 3763
June 25, 2007

